UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

ATHENEX PHARMA SOLUTIONS, LLC and ATHENEX PHARMACEUTICAL DIVISION, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Defendants.	Case No. 18-cv-00896-GWC

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(1)

TABLE OF CONTENTS

I. Introduction 1

II. Statement of Facts 5

A. Statutory Framework for New Drug Approvals 5
B. DQSA: Congress' Statutory Regime for Bulk Compounding 6
C. Interim Policy: FDA's Implementation of the DQSA 7
D. Athenex Did Not Disclose to the World its Vasopressin Products Until the Day it Filed this Complaint 8

III. Legal Standards 9

IV. Argument 10

A. Athenex Has Not Suffered a "Real and Immediate Injury" 10
1. Par Has Not Engaged in Any Affirmative Acts of Patent Enforcement against Athenex 10
2. Par's Prior Unrelated Lawsuits Do Not Establish a Jurisdictional Injury 13
3. General Public Statements Regarding Intent to Defend Patent Rights Do Not Establish a Jurisdictional Injury 16
B. To the Extent Athenex Will Suffer Any Injury, It Is Not Redressable by this Lawsuit 17
C. In the Alternative, the Court Should Exercise its Discretion and Decline Declaratory Judgment Jurisdiction 18

V. Conclusion 19

TABLE OF AUTHORITIES

CASES

AET Rail Grp., LLC v. Siemens Transp Sys., Inc.,
No. 08-CV-6442, 2009 WL 5216960 (W.D.N.Y. Dec. 30, 2009) 19

Andrx Pharm., Inc. v. Biovail Corp.,
276 F.3d 1368 (Fed. Cir. 2002) 5

Asia Vital Components Co. v. Asetek Denmark A/S,
837 F.3d 1249 (Fed. Cir. 2016) 10

Breckenridge Pharm., Inc. v. Everett Labs. Inc.,
No. 09-80015-CIV, 2009 WL 654214 (S.D. Fla. Mar. 11, 2009) 12, 13, 16

Bridgelux, Inc. v. Cree, Inc.,
No. C 06-6495 PHL, 2007 WL 2022024 (N.D. Cal. July 9, 2007) 17

BroadSign Int'l, LLC v. T-Rex Prop. AB,
No. 16 CV 04586-LTS, 2018 WL 357317 (S.D.N.Y. Jan. 10, 2018) 10, 16

Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Research,
No. 14 CIV. 2256 PAC, 2014 WL 6765996 (S.D.N.Y. Dec. 1, 2014) 17

Danisco U.S. Inc. v. Novozymes A/S,
744 F.3d 1325 (Fed. Cir. 2014) 10

Document Sec. Sys., Inc. v. Adler Techs., Inc.,
No. 03-CV-6044, 2008 WL 596879 (W.D.N.Y. Feb. 29, 2008) 15

Edmunds Holding Co. v. Autobytel Inc.,
598 F. Supp. 2d 606 (D. Del. 2009) 17

First Quality Baby Prods., LLC v. Kimberly-Clark Worldwide, Inc.,
No. 1:CV-09-0354, 2009 WL 1675088 (M.D. Pa. June 15, 2009) 12, 15

Hewlett-Packard Co. v. Acceleron LLC,
587 F.3d 1358 (Fed. Cir. 2009) 10

Impax Labs., Inc. v. Medicis Pharm. Corp.,
No. C-08-0253 MMC, 2008 WL 1767044 (N.D. Cal. Apr. 16, 2008) 17

Innovative Therapies, Inc. v. Kinetic Concepts, Inc.,
599 F.3d 1377 (Fed. Cir. 2010) ..... passim

JIA Jewelry Imps. of Am., Inc. v. Pandora Jewelry, LLC,
No. CCB-11-982, 2011 WL 4566118 (D. Md. Sept. 29, 2011) 15

Mama Cares Found. v. Nutriset Societe Par Actions Cimplifiee,
825 F. Supp. 2d 178 (D.D.C. 2011) 15

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 9

Panavise Prods., Inc., v. Nat'l Prods., Inc.,
306 F. App'x 570 (Fed. Cir. 2009) 11, 15, 16

Prasco, LLC v. Medicis Pharm. Corp.,
537 F.3d 1329 (Fed. Cir. 2008) ..... passim

Sandoz Inc. v. Amgen Inc.,
No. C-13-2904 MMC, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013),
aff'd, 773 F.3d 1274 (Fed. Cir. 2014) 17

Simon v. E. Ky. Welfare Rights Org.,
426 U.S. 26 (1976) 18

True Sci. Holdings, LLC v. Mars, Inc.,
No. 2:14CV193DAK, 2015 WL 574560 (D. Utah Feb. 11, 2015) 1, 11, 12, 15

STATUTES

21 U.S.C. § 353b 6, 7

21 U.S.C. § 355 ..... 4, 5, 6, 15

28 U.S.C. § 2201 ..... 1, 9

28 U.S.C. § 2202 1

35 U.S.C. § 271(e) 4, 6, 15

OTHER AUTHORITIES

159 Cong. Rec. 14,610 (2013) 3

Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Revised Request for Nominations,
79 Fed. Reg. 37,750 (July 2, 2014) 7

FDA, Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act (2018),
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf 8

FDA, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/%20Guidances/UCM469122.pdf 7

List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 83 Fed. Reg. 43,877 (Aug. 28, 2018) 8

This is an action for a declaratory judgment asserting that this Court has subject matter jurisdiction under 28 U.S.C. §§ 2201 and 2202. Plaintiffs Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC (collectively "Athenex") seek a declaration of non-infringement and invalidity of certain patents owned by Defendants Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC's (collectively "Par"). Par respectfully moves the Court to dismiss the complaint (ECF No. 1) under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. In the alternative, Par requests that this Court exercise its discretion to decline declaratory judgment jurisdiction.

I. INTRODUCTION

Athenex's complaint announces its intention, as of August 2018, "to supply hospitals and other health care providers" with "compounded vasopressin drug products." ECF No. 1 at ¶ 25. Vasopressin is an "active pharmaceutical ingredient." *Id*. at ¶ 24. The Par patents identified in Athenex's complaint are directed to methods of increasing blood pressure by administering particular vasopressin dosage forms.

It is fundamental hornbook law that for this Court to have jurisdiction, there must exist an "actual controversy" between Athenex and Par regarding the patents at issue. To do so, Athenex's complaint must allege an "affirmative act" demonstrating Par's intent to enforce the recited patents against Athenex's compounded vasopressin products. Athenex's complaint fails to do so. In fact, Athenex does not even allege that Par knew about Athenex's newly marketed products when Athenex filed its complaint. Nor could it have so alleged, because Par first learned of Athenex's plans for its new products from the complaint and an Athenex press release made public the very day this complaint was filed. Par's lack of awareness of Athenex's products "is dispositive of the issue of subject matter jurisdiction." *See True Sci. Holdings, LLC v. Mars, Inc.*, No. 2:14CV193DAK, 2015 WL 574560, at *6 (D. Utah Feb. 11, 2015) (citing

Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1334 (Fed. Cir. 2008)). Without even having knowledge of Athenex's compounded vasopressin products, Par obviously could not have taken any affirmative act related to those products.

Unable to allege even a belief about Par's knowledge, let alone that Par took action or threatened to act regarding Athenex's planned marketing of its new products, Athenex alleges its "belief" that "Par will bring patent infringement suits against manufacturers and/or marketers of compounded vasopressin products" (ECF No. 1 at ¶ 39), based on three lawsuits between Par and unrelated entities. A plaintiff's belief that a controversy might occur in the future is simply not sufficient to allege an "actual controversy" under 28 U.S.C. § 2201. Moreover, as demonstrated below, the other lawsuits Athenex relies on for its "belief" have nothing to do with the subject matter of Athenex's claims in this action. *See* ECF No. 1 at ¶¶ 33-41. None of those cases demonstrates an intent by Par to enforce the patents at issue against Athenex's compounded vasopressin products, and together they do not constitute a "pattern of actions [that] creates a reasonable apprehension and substantial likelihood that Par will sue Athenex for the alleged infringement of the patents-in-suit." *Id.* at ¶ 42.

The first lawsuit on which Athenex relies is an Administrative Procedure Act (APA) action Par brought against the Food and Drug Administration (FDA).[1] Par's case against FDA does not evidence Par's intent to enforce the recited patents against Athenex. To the contrary, that lawsuit involves Par's claims that FDA has implemented an "Interim Policy" regarding compounded drug products that violates the Federal Food, Drug, and Cosmetic Act (FDCA), including amendments to the FDCA made by the Drug Quality and Security Act (DQSA), and the APA.

[1] *Par Sterile Products, LLC v. Hargan*, 1:17-cv-02221 (D.D.C.).

Traditionally, the act of pharmacy "compounding" a medication meant that a pharmacist prepared a specific dosage form based on an individual patient's needs and a specific patient prescription from a physician. FDA historically did not regulate this patient-by-patient compounding process. However, when unregulated manufacturing of bulk compounded drugs resulted in "one of the worst public health disasters in our country's history," (*see* 159 Cong. Rec. 14,610, 14,650 (2013) (statement of Rep. Murphy)), Congress responded by passing the DQSA in 2013, which allowed bulk compounding of specific drug substances only if FDA determines that certain statutory requirements are met.

Following the passage of the DQSA, FDA issued an "Interim Policy on Compounding Using Bulk Drug Substances," which allowed bulk compounding of a list of substances, without a determination that the listed bulk compounded drugs would meet the DQSA requirements. In October 2017, after lengthy discussions with FDA about its "Interim Policy," Par filed its APA lawsuit. In January 2018, Par and FDA agreed to stay that lawsuit, at FDA's request, to give FDA time to implement the mandates under the DQSA. While FDA was at work on those mandates, Athenex apparently made a calculated decision to launch its bulk compounded vasopressin products under FDA's "Interim Policy" and file this lawsuit.

In the APA lawsuit, Par moved for preliminary relief enjoining FDA's "Interim Policy" or more narrowly enjoining the authorization of bulk compounding of vasopressin. Shortly thereafter, FDA published its initial determination that bulk compounded vasopressin products (such as Athenex's) do not meet the requirements for permissible bulk compounding under the DQSA. In September 2018, Par agreed with FDA to another brief stay of the case, to allow FDA to finalize its rulemaking. FDA is expected to use its best efforts to publish its final rule by

December 31, 2018. Simply stated, Par's APA lawsuit does not evidence any intent by Par to enforce the recited patents against Athenex's compounded vasopressin products.

The second lawsuit on which Athenex relies is a lawsuit Par brought to protect its trade secrets. In August 2017, Par sued QuVa Pharma, Inc. ("QuVa"), a compounding company founded by former Par employees, for misappropriating Par's trade secrets.[2] In March 2018, the U.S. District Court for the District of New Jersey preliminarily enjoined QuVa's use of those trade secrets. Par's trade secret misappropriation lawsuit does not evidence any intent by Par to enforce the recited patents against Athenex's compounded vasopressin products.

The third lawsuit on which Athenex relies is Par's lawsuit against Eagle Pharmaceuticals, Inc. ("Eagle").[3] Eagle filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of Par's Vasostrict® product—something Athenex has not done. The Hatch-Waxman amendments to the FDCA provide specific jurisdiction to litigate the infringement of Par's patents listed in what is known as the FDA "Orange Book" prior to the approval of Eagle's ANDA. 21 U.S.C. § 355(j); 35 U.S.C. § 271(e). To be clear, Eagle's generic ANDA product is not a compounded vasopressin product and Athenex's compounded vasopressin products are not generic ANDA products. Par's Hatch-Waxman lawsuit against Eagle has nothing to do with whether Par intends to enforce its "Orange Book" patents against Athenex's compounded vasopressin products.

Given Par's lack of knowledge of Athenex's compounded vasopressin products as of the filing of Athenex's complaint, the allegations in the complaint are facially insufficient to establish subject matter jurisdiction. Par's three unrelated lawsuits do not show a "pattern" that

---

[2] *Par Pharmaceutical, Inc. v. QuVa Pharma, Inc.*, 2:17-cv-06115 (D.N.J.).

[3] *Par Pharmaceutical, Inc. v. Eagle Pharmaceuticals, Inc.*, 1:18-cv-00823 (D. Del.).

creates a "substantial likelihood that Par will sue Athenex for the alleged infringement of the patents-in-suit." ECF No. 1 at ¶ 42. Athenex's "belief," which is really just Athenex's speculation, is insufficient to establish that Par has caused any injury or made a threat of future injury as is required to allege an existing "actual controversy." Indeed, to the extent that Athenex alleges injury based on some possible future disruption of its "plans to market its compounded vasopressin drug products" (*id.*), the affirmative acts that may result in that injury arise not from Par's Orange Book patents, but from FDA's implementation of the DQSA.

Because Athenex's complaint fails to allege an "actual controversy" between Par and Athenex, this Court should dismiss the complaint in its entirety. In the alternative, the Court should exercise its discretion to decline jurisdiction. Resolution of this matter will not resolve whether Athenex is able to market its compounded vasopressin products when FDA publishes its final rules concerning bulk compounded vasopressin products.

II. STATEMENT OF FACTS

A. Statutory Framework for New Drug Approvals

The FDCA regulates drug manufacturing, marketing, and distribution in interstate commerce, and prohibits the introduction of any "new drug" into interstate commerce absent premarket approval by FDA. 21 U.S.C. § 355(a). The Hatch-Waxman amendments to the FDCA in turn govern the approval of new and generic drugs. They are designed to balance competing interests of developing new drugs and enabling competitors to obtain FDA approval to bring follow-on drugs to the market. *See Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

The Hatch-Waxman amendments set forth a framework for resolving patent disputes relating to proposed follow-on versions of FDA-approved drugs. If an unexpired patent is listed in FDA's "Orange Book" as covering the approved drug product at issue, an applicant for a

follow-on version of that drug product must certify that it will not seek approval prior to the expiration of that patent or that the patent is invalid or will not be infringed. *See* 21 U.S.C. § 355(b)(2)(A)(i)-(iv), (j)(2)(A)(vii)(I)-(IV). The applicant must provide notice to each relevant patent owner to explain its invalidity or non-infringement rationale. *Id*. §§ 355(b)(3), (j)(2)(B).

If the patent owner then sues the applicant for infringement within 45 days, FDA must refrain from approving the follow-on application for up to 30 months to allow that litigation to proceed. *See id*. §§ 355(c)(3)(C), (j)(5)(B)(iii). Only if the patent owner does not bring suit within 45 days may the applicant bring a suit under the Declaratory Judgment Act, 28 U.S.C. § 2201, challenging the listed patents. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5).

B. DQSA: Congress' Statutory Regime for Bulk Compounding

As mentioned above, Congress enacted the DQSA in 2013, imposing restrictions on bulk compounding. The DQSA added a section, 503B, which specifically targeted "outsourcing facilities" (like Athenex) that constitute the bulk compounding industry. DQSA, Pub. L. No. 113-54, 127 Stat. 588, Title I § 102(a)(2) (2013) (codified as amended 21 U.S.C. § 353b).

Section 503B makes plain that if a compounded drug does not qualify for an exemption under the DQSA, it is subject to all the requirements of the FDCA, including the new drug approval requirements. *See* 21 U.S.C. § 353b(a). It also establishes a narrow exception for bulk compounders that register as "outsourcing facilities." 21 U.S.C. § 353b(a). Such a facility may distribute drug products compounded from bulk drug substances only if multiple statutory requirements are satisfied. *See id*.

Essentially, these provisions require the following process to authorize a substance for bulk compounding. First, FDA may not authorize bulk compounders to produce a drug simply to compete with or replace an FDA-approved drug. *See* 21 U.S.C. § 353b(a)(5). Second, FDA must make a record-based determination that bulk compounding using a particular drug

substance is necessary to satisfy a "clinical need" unmet by approved drug products. *See id.* § 353b (a)(2)(A)(i). FDA may only make such a determination after publishing a proposal in the Federal Register that includes "the rationale for such proposal," and provides "a period of not less than 60 calendar days for comment." FDA must then publish its ultimate decision in the Federal Register. *See id.* § 353b (a)(2)(A)(i)(III). Only after satisfying that statutory process, can FDA authorize bulk compounding by adding the specific drug substance to its Clinical Need List. *See id.* § 353b(a)(2) .

C. Interim Policy: FDA's Implementation of the DQSA

In 2014, FDA opened a docket to accept "nominations" of bulk drug substances for inclusion on the Clinical Need List. *See* Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Revised Request for Nominations, 79 Fed. Reg. 37,750, 37,751 (July 2, 2014). Instead of following the statutory process to determine whether to allow bulk compounding using those substances, however, FDA issued a policy treating the mere nomination of a substance as sufficient to authorize bulk compounding using that substance. *See* FDA, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Jan. 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/%20Guidances/UCM469122.pdf. Under that regime, a substance is eligible for bulk compounding if it appears in Category 1 of a list of nominated substances posted on FDA's website, even if the substance does not appear in the statutory Clinical Need List. *See id.* at 8 (stating that "FDA does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance that does not appear on the [Clinical Need List] . . . provided that" the substance is in Category 1 and certain other conditions are satisfied).

In April 2017, two compounders (QuVa and a then-unidentified company, which was later revealed to be Athenex) submitted nominations to FDA for vasopressin, and FDA then placed vasopressin in Category 1 under the Interim Policy.

In the Par lawsuit against FDA, as mentioned above, in January 2018, FDA pledged to use its best efforts to issue a draft guidance document "that proposes criteria for making clinical need determinations for purposes of establishing" the Clinical Need List. Ex.[4] A, ECF No. 13 at ¶ 3 in 17-cv-02221 (D.D.C.). FDA issued that document in March 2018. *See* FDA, Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act (2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf.

In August 2018, FDA published in the Federal Register for public comment FDA's proposal that no clinical need exists for compounded vasopressin. List of Bulk Drug Substances for Which There is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 83 Fed. Reg. 43,877, 43,881-82 (Aug. 28, 2018). FDA has committed to using its best efforts to publish a final clinical need determination by the end of 2018. Ex. B, ECF No. 53 at ¶ 9 in 17-cv-02221 (D.D.C.).

D. Athenex Did Not Disclose to the World its Vasopressin Products Until the Day it Filed this Complaint

Par first learned of Athenex's compounded vasopressin products on August 13, 2018, through the filing of Athenex's declaratory judgment complaint, and Athenex's press release dated that same day, announcing the launch of its compounded vasopressin products. Pera

[4] "Ex." refers to the corresponding exhibit to the Declaration of Michael Brady, submitted herewith.

Decl.[5] ¶ 2; Ex. C (Athenex press release). Athenex had not previously notified Par of its compounded vasopressin products, and Par, without any knowledge of Athenex's products, had not contacted Athenex regarding its compounded vasopressin products prior to the filing of Athenex's complaint. Pera Decl. ¶¶ 3-4. Prior to August 13, 2018, Par simply had no knowledge that Athenex intended to launch a compounded vasopressin product. *Id*. at ¶¶ 5-6. As it turned out, Athenex was the unidentified compounder that had its attorneys submit its anonymous nomination to FDA in April 2017 for compounded vasopressin, which Athenex first disclosed on the day it filed this complaint. *See* Ex. D, ECF No. 19-1 at 20 in 17-cv-02221 (D.D.C.).

III. LEGAL STANDARDS

The Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., provides: "In a case of actual controversy within its jurisdiction,… any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration…." 28 U.S.C. § 2201(a). An "actual controversy" means what it says, i.e., that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118, 127 (2007).

It is the bedrock rule of declaratory judgment jurisdiction that "a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco*, 537 F.3d at 1339 (emphasis in original). When a patent is at issue, as

[5] "Pera Decl." refers to the Declaration of Antonio Pera, submitted herewith.

here, jurisdiction "generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *Id*. Instead, "conduct that can be reasonably inferred as demonstrating intent to enforce a patent" is required. *BroadSign Int'l, LLC v. T-Rex Prop. AB*, No. 16 CV 04586-LTS, 2018 WL 357317, at *3 (S.D.N.Y. Jan. 10, 2018) (quoting *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1363 (Fed. Cir. 2009)).

Of course, subject matter jurisdiction must exist at the time the claim for declaratory judgment was filed. *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1384 (Fed. Cir. 2010).

IV. ARGUMENT

A. Athenex Has Not Suffered a "Real and Immediate Injury"

1. Par Has Not Engaged in Any Affirmative Acts of Patent Enforcement against Athenex

There is simply no allegation that Par has engaged in any affirmative acts that have caused Athenex to suffer a jurisdictional injury, or that threatened a future injury. Athenex does not allege that Par was aware of Athenex's compounded vasopressin products, let alone that Par had any intent to enforce its patents against Athenex at the time it filed its declaratory judgment complaint.[6] Nor could it, because Par was first informed of Athenex's compounded vasopressin products by the filing of Athenex's complaint and Athenex's simultaneous press release. Indeed,

[6] Nor has Athenex alleged other acts between Par and Athenex that demonstrate an actual controversy under the totality of the circumstances. *Cf. Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330-31 (Fed. Cir. 2014) (there, the declaratory judgment defendant repeatedly asserted that plaintiffs' product would infringe its patent when issued, and had previously sued plaintiff for infringement on related products); *Asia Vital Components Co. v. Asetek Denmark A/S*, 837 F.3d 1249, 1253-54 (Fed. Cir. 2016) (this case involved a history of hostile interactions between the parties, including threats by declaratory judgment defendant to plaintiff's customers regarding infringement of the patents).

Par's "lack of awareness of the infringing product is dispositive of the issue of subject matter jurisdiction." *True Sci.*, 2015 WL 574560, at *6 (citing *Prasco*, 537 F.3d at 1334).

The Federal Circuit has held that where the patentee has not committed an affirmative act evidencing an intent to enforce its patents against the declaratory judgment plaintiff, as is the case here, no subject matter jurisdiction exists. *See, e.g.*, *Innovative Therapies*, 599 F.3d at 1380 (no jurisdiction where patentee had not seen any product produced by plaintiff and had not charged plaintiff with infringement as to such device); *Panavise Prods., Inc., v. Nat'l Prods., Inc.*, 306 F. App'x 570, 573 (Fed. Cir. 2009) (no jurisdiction where there was no evidence that patentee was aware of the product at issue before the filing of the declaratory judgment action). Here, there is a "complete lack of evidence of a defined, preexisting dispute" between Athenex and Par concerning Athenex's compounded vasopressin products at the time of the complaint. *See Prasco*, 537 F.3d at 1340. The mere existence of Par's vasopressin patents, without more, does not create a case of actual controversy.

The facts in *Prasco* are instructive, and demonstrate that no jurisdiction exists here. Prasco filed a declaratory judgment complaint against Medicis, seeking a declaration that its drug product Oscion did not infringe four of Medicis' patents. 537 F.3d at 1334. Medicis, like Par here, did not know about the existence of Oscion until the complaint was served. *Id.* Prasco asserted that Medicis caused Prasco an actual harm, namely, uncertainty that Medicis would bring an infringement suit against it. *Id.* at 1338. Prasco did not allege that Medicis had actually restrained its right to freely market Oscion at the time the complaint was filed, and the Court found that Prasco launched its Oscion product notwithstanding Medicis' patents and the alleged perceived uncertainty. *Id.* at 1338, 1339. The Court held that the threat of future infringement suit was not an immediate and real controversy:

> [D]efendants have not accused Prasco of infringement or asserted any rights to Oscion, nor have they taken any actions which imply such claims. Instead, all we have before us is Prasco's allegation that its product does not infringe the defendants' patents. The defendants' lack of any "concrete claim of a specific right" is an important factor weighing against a finding of an actual controversy, particularly given that there has been no actual injury. . . . None of the facts on which Prasco relies overcome the complete lack of evidence of a defined, preexisting dispute between the parties concerning Oscion.

Id. at 1340.

To the same effect is *Breckenridge Pharm., Inc. v. Everett Labs. Inc*., No. 09-80015-CIV, 2009 WL 654214 (S.D. Fla. Mar. 11, 2009), where plaintiff Breckenridge filed a declaratory judgment complaint seeking declarations that its multivitamin product did not infringe any valid claim of Everett's patents. *Id*. at *1. Like Athenex in this case, Breckenridge began to market its multivitamin on the very day it filed its complaint, and did not allege that Everett had knowledge of Breckenridge's product. *Id*. The Court granted the motion to dismiss, finding that the complaint did not allege any affirmative acts by Everett with respect to the assertion of the subject patents against Breckenridge's multivitamin. *Id.* at *3; *see also First Quality Baby Prods., LLC v. Kimberly-Clark Worldwide, Inc.*, No. 1:CV-09-0354, 2009 WL 1675088, at *4 (M.D. Pa. June 15, 2009) (no jurisdiction where the patentee had not communicated with the plaintiff, made any threats of infringement, or was ever aware of the plaintiff's product prior to the declaratory judgment action); *True Sci.*, 2015 WL 574560 at *5 (no jurisdiction where patentee "has not and cannot threaten an infringement action when it does not know anything about the product").

The absence of any evidence that Par had knowledge of Athenex's vasopressin products shows that Athenex did not face an imminent risk of injury at the time it filed its complaint. As in the above cases, Par had taken no affirmative acts enforcing the subject patents against Athenex's compounded vasopressin products. Athenex's marketing and selling of its

compounded vasopressin products, by itself, does not suffice to create a jurisdictional injury in fact. *See Prasco*, 537 F.3d at 1338 (potential competitor "is legally free to market its product in the face of an adversely-held patent"). Indeed, Par's patents did not stop Athenex from doing so. Athenex freely admits it offered its products for sale in August the day it filed its lawsuit.

Because Par had no knowledge of Athenex's compounded vasopressin products prior to the suit, no subject matter jurisdiction exists over this lawsuit.

2. Par's Prior Unrelated Lawsuits Do Not Establish a Jurisdictional Injury

Athenex alleges that three of Par's prior lawsuits demonstrate a "pattern" of actions that create a "likelihood" that Par will sue Athenex for patent infringement. ECF No. 1 at ¶ 42. Not so. None of these three lawsuits has anything to do with whether Athenex's vasopressin products infringe Par's valid patents. None of these three lawsuits establishes declaratory judgment jurisdiction here.

Par's lawsuit against the FDA does not involve Par enforcing the subject patents against a compounded vasopressin product. Indeed, no patents are at issue in the APA litigation. Rather, Par's litigation with FDA seeks a declaration that FDA's Interim Policy violates the congressional mandates under the DQSA and the APA. *See, e.g.*, *Breckenridge*, 2009 WL 654214 at *3 (rejecting argument that prior lawsuits establish a jurisdictional injury, where the prior lawsuits did not involve the same products or the same patents in the complaint).

Athenex alleges that Par's statements in the APA litigation concerning the Hatch-Waxman amendments to the FDCA demonstrate a reasonable likelihood of a patent infringement suit against Athenex. ECF No. 1 at ¶ 35. But Par's policy arguments in the APA litigation have no bearing here, where Athenex alleges that its compounded vasopressin products do not fall under the Hatch-Waxman provisions. *Id*. at ¶ 28 ("Athenex's compounded vasopressin products

are exempted from certain FDA drug approval requirements including the scheme established by the Hatch-Waxman Amendments for resolving patent disputes."). Simply put, Par's arguments in the APA case about FDA's failure to implement the DQSA do not establish this Court's jurisdiction over Athenex's declaratory judgment claims. Whether Athenex may someday decide to comply with the Hatch-Waxman Act and file an ANDA is too speculative to establish jurisdiction. *See Innovative Therapies*, 599 F.3d at 1383-84 (subsequent events can "not change the fact that no actual controversy existed at the time the original complaint was filed").

Similarly, Par's lawsuit against QuVa does not involve Par enforcing the subject patents against a compounded vasopressin product. The QuVa litigation relates to QuVa's—and certain of Par's former employees'—misappropriation of Par's trade secrets. Par has not claimed that QuVa's products infringe Par's patents. *See* ECF No. 1 at ¶ 37. Athenex states its "belief" that "when answering QuVa's counterclaims, Par *will* assert that QuVa's compounded vasopressin product infringes Par's Orange Book-listed patents, i.e., the patents-in-suit." *Id.* (emphasis added). But speculation about future actions cannot establish jurisdiction. *See Prasco*, 537 F.3d at 1340 (no jurisdiction where "all we have before us is Prasco's allegation that its product does not infringe the defendants' patents").

Par's litigation against Eagle likewise does not involve Par enforcing the subject patents against a compounded vasopressin product. Par sued Eagle for patent infringement, based on Eagle's filing of an ANDA seeking FDA approval to market generic vasopressin. But Eagle's generic ANDA product falls under the Hatch-Waxman framework, where Congress specifically provided for subject matter jurisdiction. 21 U.S.C. § 355(j); 35 U.S.C. § 271(e). Athenex has alleged that such subject matter jurisdiction does not apply here. ECF No. 1 at ¶ 28.

Par's actions against a different entity, under a different statutory framework, regarding an unrelated product, fail to establish an affirmative act of patent infringement directed towards Athenex. *See Innovative Therapies*, 599 F.3d at 1382 ("the fact that [a defendant] had filed infringement suits against other parties for other products does not, in the absence of any act directed toward [the declaratory judgment plaintiff], meet the minimum standard discussed in *MedImmune*"); *see also* this Court's decision in *Document Sec. Sys., Inc. v. Adler Techs., Inc.*, No. 03-CV-6044, 2008 WL 596879, at *11 (W.D.N.Y. Feb. 29, 2008) (infringement action against an unrelated third party "does not supply a definite, concrete, real and substantial controversy between the parties to this action"); *Mama Cares Found. v. Nutriset Societe Par Actions Cimplifiee*, 825 F. Supp. 2d 178, 183 (D.D.C. 2011) (mandating an "act directed toward [plaintiffs]" regardless of whether defendant maintained an active portfolio of patent enforcement litigation); *First Quality*, 2009 WL 1675088 at *4 (no jurisdiction despite patentee's history of suing others on the subject patent); *True Sci.*, 2015 WL 574560 at *5 (no jurisdiction despite other litigation between the parties regarding different products); *JIA Jewelry Imps. of Am., Inc. v. Pandora Jewelry, LLC*, No. CCB-11-982, 2011 WL 4566118, at *3-4 (D. Md. Sept. 29, 2011) (no jurisdiction even where defendant asserted the subject patent against a company similarly situated but unrelated to plaintiff).

The facts in the *Panavise* case are instructive, and demonstrate that no jurisdiction exists here. Panavise alleged in its complaint that NPI had asserted the patent at issue against various entities, and that on "information and belief" NPI had observed Panavise's device. 306 F. App'x at 572. The Federal Circuit affirmed the dismissal of the complaint for lack of subject matter jurisdiction. There was no evidence that NPI observed Panavise's product or was even aware of its existence before the filing of the complaint. *Id*. at 573. And the six lawsuits in which NPI

asserted infringement of the patent against other products did not show immediacy. *Id*. "The lack of any evidence that NPI plans to assert the '420 patent against Panavise prevents us from concluding that Panavise faces any immediate threat of future injury." *Id*. Here, the fact that Par asserted infringement of the recited patents based on a third party's filing of an ANDA to market a product that is unrelated to Athenex's compounded vasopressin products likewise does not show an immediate threat of future injury to Athenex.

Similarly, in *Breckenridge*, the District Court held that Everett's prior lawsuits against the plaintiff and other competitors, none of which involved the same products or the patents at issue, did not show an actual controversy. 2009 WL 654214, at *3.

In sum, Par's other lawsuits on which Athenex relies do not constitute "conduct that can be reasonably inferred as demonstrating intent to enforce a patent" against Athenex. *BroadSign*, 2018 WL 357317, at *3. Those unrelated lawsuits—regarding FDA's Interim Policy on compounding, trade secret misappropriation by former employees, and an ANDA to market an FDA-approved generic vasopressin product—do not establish declaratory judgment jurisdiction in this case. Even assuming Par had knowledge of Athenex's vasopressin products when Athenex filed its complaint (which Par undisputedly did not), these lawsuits fail to show a case or controversy with respect to Athenex.

3. General Public Statements Regarding Intent to Defend Patent Rights Do Not Establish a Jurisdictional Injury

Athenex further alleges that public statements by Par's parent company Endo International PLC ("Endo") that it will "vigorously defend and prosecute the [FDA and QuVa lawsuits] as appropriate," "protect our intellectual property rights," and "pursue all available legal and regulatory avenues…" further create a "reasonable apprehension" of suit. ECF No. 1 at ¶¶ 36, 38, 42. Again, Athenex is incorrect.

Mere public statements by a patent owner that it defends the patents that it owns "do not suffice to show an imminent threat of litigation." *Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Research*, No. 14 CIV. 2256 PAC, 2014 WL 6765996, at *4 (S.D.N.Y. Dec. 1, 2014) (quoting *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 WL 6000069, at *2-3 (N.D. Cal. Nov. 12, 2013), *aff'd*, 773 F.3d 1274 (Fed. Cir. 2014)). *See also, e.g.*, *Bridgelux, Inc. v. Cree, Inc.*, No. C 06-6495 PHL, 2007 WL 2022024, at *9 (N.D. Cal. July 9, 2007) (defendant's "unremarkable" public statements at industry meetings that it would defend its patents did not show a real controversy); *Impax Labs., Inc. v. Medicis Pharm. Corp.*, No. C-08-0253 MMC, 2008 WL 1767044, at *3 (N.D. Cal. Apr. 16, 2008) (public statements that defendant would vigorously enforce the patents at issue, made before it had knowledge of plaintiffs' drug product, did not show a real controversy); *Sandoz*, 2013 WL 6000069, at *2 (public statements "that its patents cover [the product at issue], and that it defends the patents it owns" did not show a real controversy); *Edmunds Holding Co. v. Autobytel Inc.*, 598 F. Supp. 2d 606, 608 n.4, 610 (D. Del. 2009) (defendant's CEO's stated general intent to "protect and enforce its rights with respect to its intellectual property," and suits against eight other companies on the same patent, without more, did not show a real controversy). Moreover, Endo's statements preceded Par's knowledge of Athenex's vasopressin products, and were not directed at Athenex in particular. Such statements cannot constitute a threat of enforcement against a product that Par has not seen or evaluated for infringement. *Innovative Therapies*, 599 F.3d at 1381.

B. To the Extent Athenex Will Suffer Any Injury, It Is Not Redressable by this Lawsuit

As explained above, Athenex has failed to allege that Par has committed any affirmative act demonstrating an intent to enforce its patents against Athenex's compounded vasopressin

products. The only injury Athenex alleges (prospective as it is) is a disruption to its newly announced plans to market its vasopressin products. ECF No. 1 at ¶ 42. But the source of this "injury" is FDA's implementation of the DQSA—not Par's Orange Book patents. Athenex is required to allege that its alleged injury is "caused by defendants" (*Prasco*, 537 F.3d at 1339). It has not done so.

Whether Athenex is allowed to market its compounded vasopressin products under the DQSA is an issue for FDA to determine. This patent infringement lawsuit has nothing to do with FDA's determination. Given that the ultimate relief that Athenex seeks—the ability to market its compounded vasopressin drug products—rises and falls with the FDA's determination of whether vasopressin can be compounded under the DQSA, Athenex's alleged injury is simply not redressable by this case. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) ("the 'case or controversy' limitation of Art. III… requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court").

C. In the Alternative, the Court Should Exercise its Discretion and Decline Declaratory Judgment Jurisdiction

Were the Court to find, contrary to Par's positions as explained above, that jurisdiction is proper here, the Court should decline to exercise jurisdiction in this case. FDA has already made a preliminary determination that there is no statutory clinical need for bulk compounded vasopressin. Should FDA confirm that position after the public comment period (and FDA has pledged to use best efforts to do so by the end of the year), Athenex will not be allowed to continue to sell its compounded vasopressin products. Because this case will not resolve the issues before the FDA, it will not "serve a useful purpose in clarifying and settling the legal relations in issue" or "afford relief from the uncertainty, insecurity, and controversy giving rise

to the proceeding." *AET Rail Grp., LLC v. Siemens Transp. Sys., Inc.*, No. 08-CV-6442, 2009 WL 5216960, at *6 (W.D.N.Y. Dec. 30, 2009).

V. CONCLUSION

For the foregoing reasons, the Court should grant Par's Motion to Dismiss for lack of subject matter jurisdiction.

DATED: Buffalo, New York
October 22, 2018

HAGERTY & BRADY

By: s/ Michael A. Brady
MICHAEL A. BRADY, ESQ.
Attorneys for Defendants PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC
69 Delaware Avenue, Suite 1010
Buffalo, NY 14202-3875
Telephone: (716) 856-9443
Fax: (716) 856-0511

Of Counsel:

Daniel G. Brown
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022-4834
Telephone: (212) 906-1200
Fax: (212) 751-8464

Jennifer Koh
Yi Sun
LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
Telephone: (858) 523-5400
Fax: (858) 523-5450